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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/532,489	02/21/2006	Matthew Scanlan	029065.51088US2	3837

23911 7590 01/25/2007
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EXAMINER	
NATARAJAN, MEERA	
ART UNIT	PAPER NUMBER
1609	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
31 DAYS	01/25/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/532,489	SCANLAN ET AL.	
	Examiner	Art Unit	
	Meera Natarajan	1609	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *February 21, 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6-19,21-23,25-31 and 33-47* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-4,6-19,21-23,25-31 and 33-47* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

To have a general inventive concept under PCT rule 13.1, the inventions need to be linked by a special technical feature. The special technical feature recited in claim 1 is a substantially pure immunoglobulin molecule which binds specifically to A34 antigen. In view of this Nustad et al. (Tumour Biol. 1998; 19(4):293-300) reads on the claim. Nustad et al. teaches specificity and affinity of 30 monoclonal antibodies against alpha-fetoprotein including said molecule in Claim 1, A34. Therefore the technical feature recited in claim 1 is not special. Accordingly the groups are not so linked as to form a single general concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-4, 6-7, 25-31, 35-47, drawn to a substantially pure immunoglobulin molecule and a composition.

Group II, claim(s) 8-9, drawn to a method of reducing the effects in a patient of a cancer that expresses A34 antigen.

Group III, claim(s) 10-13, drawn to an isolated polynucleotide comprising an isolated polynucleotide encoding A34 protein, an expression vector, and a host cell.

Group IV, claim(s) 14-16 drawn to an isolated polypeptide molecule comprising A34, or an antigenic fragment of said A34 and a polypeptide.

Group V, claim(s) 17-18, drawn to a method of diagnosing cancer characterized by the presence of A34 antigen in cancer cells.

Group VI, claim(s) 19, 33, drawn to a hybridization assay and a method for determining if cancer cells, which express A34, are present in a sample

Group VII, claim(s) 21-23, drawn to a method for determining regression, progression, or onset of a cancerous condition.

Group VIII, claim(s) 33, drawn to a method for determining if cancer cells which express A34 are present in a sample.

Group IX, claim(s) 34, drawn to an isolated polynucleotide molecule.

2. The inventions listed as Groups I-IX do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: As set forth above, in view of the teaching of Nustad et al. the groups are not so linked as to form a single general concept under PCT Rule 13.1 because the technical feature of claim 1 is not special.

3. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

If Group I is elected, the species are as follows:

Anti-cancer agent (Claim 29):

A. radioisotopes

B. chemotherapeutic agents

C. cytotoxic agents

Chemotherapeutic or cytotoxic agent (Claim 31):

A. QFA

B. antifolates

C. BCNU

D. mercaptopurine

E. methotrexate

F. docetaxel

G. adriamycin

H. calicheamicin

I. cellular toxin

J. bacterial toxin

K. pseudomonas exotoxin

L. ricin

M. diphtheria toxin

CDR3 sequence (select one or combination) Claim 36:

A. SEQ ID NO: 34

B. SEQ ID NO: 37

C. SEQ ID NO: 40

D. SEQ ID NO: 43

E. SEQ ID NO: 46

F. SEQ ID NO: 49

Applicant is required, in reply to this action, to elect a single species of anti-cancer agent, chemotherapeutic or cytotoxic agent, and CDR3 sequence to which the

claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

4. The claims are deemed to correspond to the species and claims listed above. The following claim(s) are generic: claims 29, 31, and 36.

5. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The special technical feature recited in claim 1 is a substantially pure immunoglobulin molecule which binds specifically to A34 antigen. In view of this Nustad et al. (Tumour Biol. 1998; 19(4):293-300) reads on the claim. Nustad et al. teaches specificity and affinity of 30 monoclonal antibodies against alpha-fetoprotein including said molecule in Claim 1, A34.

6. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject

matter and different searches in the patent literature, restriction for examination purposes as indicated is proper.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Meera Natarajan Ph.D. whose telephone number is 571-272-0235. The examiner can normally be reached on Monday-Thursday, 7:30AM-5:00PM, ALT. Friday. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mary Mosher can be reached on 571-272-0906. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MN

ZACHARIAH LUCAS
PATENT EXAMINER